

10/522450

IVS OBTURATOR INSTRUMENT AND PROCEDUREREPLACED BY
ART 34 AMDTCROSS-REFERENCE TO RELATED APPLICATIONS

The present disclosure claims priority to U.S. Provisional Application Serial No. 60/397,905, filed July 23, 2002 and entitled IVS OBTURATOR.

BACKGROUND1. Technical Field

The technical field relates to insertion instrumentation for inserting material into the body and, more particularly, to an insertion tool and method for inserting a support structure or material into the body to provide a support to the urethra.

2. Background of Related Art

One problem occurring in women due to the onset of advanced age or trauma is urinary stress incontinence. Several therapies have been developed to correct or alleviate this condition, such as, for example drug therapies and surgical procedures. In some cases it is necessary to implant a temporary or permanent structure to support the midline of the urethra to control discharge.

Several surgical procedures have been developed to position a support against the urethra. Many of these procedures require the use and installation of bone anchors to affix the ends of the support to the pubic bone. These procedures are fairly invasive and require complex instruments to install the bone anchors in the pubic bone.

One exemplary device and method of inserting, in a minimally invasive manner, a sling support within the body to support the urethra is disclosed in certain embodiments of U.S. Patent No. 5,112,344 to Petros, the entire disclosure of which is hereby incorporated by reference herein. The Petros reference discloses the use of an instrument to insert a length of tape through incisions in the abdomen and the vagina so that the tape supports the urethra. No bone

anchors or other auxiliary structures are used to anchor the tape. While inserting the tape into the body using the instrument, the instrument passes through the patient's body on either side of the bladder. Although this instrument is designed to safely pass from the incision in the vagina to the incision in the abdomen, surgeons typically perform a cystoscopy to check the integrity of the bladder.

It is desirable to have other methods of inserting, in a minimally invasive manner, support structure or material into the body without having to pass an instrument through the body on either side of the bladder.

SUMMARY

In one aspect of the present invention, a surgical instrument for passing a material into a body in a minimally invasive procedure comprises a first member having a longitudinal section defining a longitudinal axis and an arcuate section extending distally from the longitudinal section; the arcuate section has at least two different radii of curvature. The shape of the first member facilitates the passing of the material into the body, in a minimally invasive procedure. The shape of the first member enables a material to be placed inside the body in a minimally invasive procedure so that the material extends through the obturator foramen.

In certain preferred embodiments, the first member comprises a hollow outer tubular member. A stylet is at least partially movable within the outer tubular member and engageable with a material to pass the material within the body. The hollow outer tubular member and stylet enable the surgeon to remove the stylet from the outer tubular member and reinsert the stylet in the opposite position with respect to the outer tubular member. This structure also facilitates the placement of the material so that the material extends from a first side of the pelvis to a second side of the pelvis.

Preferably, a proximal portion of the arcuate section curves away from the longitudinal axis in a first direction

distal end may comprise a blunt conical tip. In other embodiments, the stylet has a distal end that is sharp.

In a further aspect of the present invention, a surgical instrument for passing a material into a body in a minimally invasive procedure, comprises a first member having a longitudinal section defining a longitudinal axis and an arcuate section extending distally from the longitudinal section. The arcuate section is dimensioned and curved whereby when in use and in position in the body, the arcuate section extends from the skin over the obturator foramen, through the obturator foramen, to the vaginal wall. The shape of the first member facilitates the passing of the material into the body, in a minimally invasive procedure. The shape of the first member enables a material to be placed inside the body in a minimally invasive procedure so that the material extends through the obturator foramen.

BRIEF DESCRIPTION OF THE DRAWINGS

Various embodiments are described herein with reference to the drawings wherein:

FIG. 1 is a side view of an instrument for use in a surgical procedure in accordance with an embodiment of the present invention;

FIG. 2 is a side view of an outer member of the instrument in accordance with the embodiment of FIG. 1;

FIG. 3 is a bottom view of the outer member of the instrument in accordance with the embodiment of FIGS. 1 and 2;

FIG. 4 is a side view of a stylet of the instrument in accordance with the embodiment of FIGS. 1-3;

FIG. 5 is a perspective view of a length of material used with the instrument in accordance with the embodiment of FIGS. 1-4;

FIG. 6 is a sketch showing the relation of the vagina to the pelvis;

FIG. 7 is a black and white photograph of the vaginal area during an initial stage of a surgical procedure in accordance with a further embodiment of the invention;

The outer tubular member desirably has a handle at a proximal end thereof. In certain preferred embodiments, the handle has a laterally extending portion. The arcuate section defines a first plane and the wing defines a second plane substantially perpendicular to the first plane.

The surgical instrument preferably includes a material and, in certain preferred embodiments, wherein the material comprises a generally flat tape. At least one end of the tape may be cut at an angle for ease of threading the tape into the stylet, in embodiments in which the stylet comprises a slot for receipt of the at least one end. The tape desirably comprises a material including multifilament strands, which may comprise polypropylene strands. The material may comprise a generally flat tape and the stylet may have a proximal end adapted to receive an end of the tape. The material may comprise an absorbable material.

The stylet is desirably positioned in the tubular member so that the proximal end of the stylet is located adjacent a proximal end of the tubular member. In certain preferred embodiments, the stylet has a distal end that is blunt. The distal end may comprise a blunt conical tip. In other embodiments, the stylet has a distal end that is sharp.

In yet another aspect of the present invention, a surgical instrument for passing a material into a body comprises a tubular member having a longitudinal section defining a longitudinal axis and an arcuate section extending distally from the longitudinal section. The arcuate portion has a proximal portion which curves away from the longitudinal axis in a first direction and a distal portion which curves toward the longitudinal axis in a second direction. The shape of the first member facilitates the passing of the material into the body, in a minimally invasive procedure. The shape of the first member enables a material to be placed inside the body in a minimally invasive procedure so that the material extends through the obturator foramen.

A stylet is at least partially movable within the outer tubular member and engageable with a material to pass the material within the body. The hollow outer tubular

comprises a slot for receipt of the at least one end of the tape desirably comprises a material including multifilament strands, which may comprise polypropylene strands. The material may comprise a generally flat tape and the stylet may have a proximal end adapted to receive an end of the tape. The material may comprise an absorbable material.

The stylet is desirably positioned in the tubular member so that the proximal end of the stylet is located adjacent a proximal end of the tubular member. In certain preferred embodiments, the stylet has a distal end that is blunt. The distal end may comprise a blunt conical tip. In other embodiments, the stylet has a distal end that is sharp.

In a further aspect of the present invention, a method of suspending a portion of the urethra with a length of material comprises the steps of providing a surgical instrument having an outer tubular member including a longitudinal proximal end and a curved distal end and a stylet movable within the tubular member and configured to hold an end of the length of material. The method includes positioning the stylet within the tubular member. A vaginal incision and an incision located over the obturator foramen are made. The curved distal end of the surgical instrument is passed through the incision over the obturator foramen. The method includes manipulating the surgical instrument such that the curved distal end passes through the obturator foramen and out the vaginal incision. A proximal end of the stylet is engaged with a first end of the length of material, and the stylet is drawn through the tubular member to draw a portion of the length of material from the incision over the obturator foramen and through the vaginal incision.

The outer tubular member may be withdrawn through the incision over the obturator foramen leaving the length of material extending through the obturator foramen and out the vaginal incision. The step of passing the curved distal end of the surgical instrument through the incision over the obturator foramen desirably includes rotating the surgical instrument approximately 30 degrees upward in relation to the body. The surgical instrument is desirably elevated to position the curved distal end through the obturator foramen.

**REPLACED BY
ART 34 AMDT**

The surgical instrument is rotated to pass the curved distal end through the obturator foramen and out the vaginal incision.

In a further aspect of the present invention, a method of suspending a portion of the urethra comprises the steps of passing a curved distal end of a surgical instrument through the body so that the instrument extends between a vaginal incision and a skin incision located over the obturator foramen. The surgical instrument has an outer tubular member including a longitudinal proximal end and a curved distal end and a stylet movable within the outer tubular member. The stylet is drawn through the body to draw the length of material through the body, extending between the vaginal incision and the incision over the obturator foramen.

The step of passing the curved distal end of the instrument desirably includes inserting the curved distal end of the instrument into the incision over the obturator foramen and moving the curved distal end through the obturator foramen, out the vaginal incision. The step of passing the curved distal end of the instrument desirably includes inserting the curved distal end into the vaginal incision. During the step of passing the curved distal end of the instrument, the stylet is desirably disposed within the outer tubular member.

The method may include, after the step of passing, withdrawing the stylet from the outer tubular member. The stylet may be reinserted in the outer tubular member so that an end of the stylet adapted to receive the material is disposed at the vaginal incision. The material is desirably disposed so that the material is received by the end of the stylet.

The step of drawing may include withdrawing the stylet through the outer tubular member, thereby drawing the material through the outer tubular member, and removing the outer tubular member through the body. The step of drawing may include withdrawing the stylet and outer tubular member from the body, thereby drawing the material through the body.

21
CLAIMS

REPLACED BY
ART 34 AMDT

1. A surgical instrument for passing a material into a body in a minimally invasive procedure comprising:

a first member having a longitudinal section defining a longitudinal axis and an arcuate section extending distally from the longitudinal section, the arcuate section having at least two different radii of curvature.

2. The surgical instrument as recited in claim 1, wherein the first member comprises a hollow outer tubular member.

3. The surgical instrument as recited in claim 2, further comprising a stylet at least partially movable within the outer tubular member and engageable with a material to pass the material within the body.

4. The surgical instrument as recited in claim 2, wherein a proximal portion of the arcuate section curves away from the longitudinal axis in a first direction and defines a first radius of curvature.

5. The surgical instrument as recited in claim 4, wherein a distal portion of the arcuate section curves toward the longitudinal axis in a second direction and defines a second radius of curvature.

6. The surgical instrument as recited in claim 5, wherein the distal portion of the arcuate section has a third radius of curvature, different from the second radius of curvature.

7. The surgical instrument as recited in claim 6, wherein the distal portion has a central section and a distalmost section, the central section having the second radius and the distalmost section having the third radius, the second radius being larger than the third radius.

8. The surgical instrument as recited in claim 6, wherein the distal portion has a central section and a distalmost section, the central section having the second radius and the distalmost section having the third radius, the second radius being smaller than the third radius.

9. The surgical instrument as recited in claim 5, wherein a portion of the distal section extends across the longitudinal axis in the second direction.

10. The surgical instrument as recited in claim 3, wherein the stylet is flexible.

11. The surgical instrument as recited in claim 3, wherein the stylet includes a slot at a first end for receipt of an end of a material.

12. The surgical instrument as recited in claim 3, wherein the stylet includes a conical tip at a second end.

13. The surgical instrument as recited in claim 12, wherein a diameter of the conical tip is greater than an inner diameter of the outer tubular member.

14. The surgical instrument as recited in claim 2, wherein the outer tubular member has a handle at a proximal end thereof.

15. The surgical instrument as recited in claim 14, wherein the handle has a laterally extending portion.

16. The surgical instrument as recited in claim 15, wherein the arcuate section defines a first plane and the wing defines a second plane substantially perpendicular to the first plane.

17. The surgical instrument as recited in claim 3, further comprising a material and wherein the material comprises a generally flat tape.

REPLACED BY
ART 34 AMDT

18. The surgical instrument as recited in claim 17, wherein at least one end of the tape is cut at an angle for ease of threading the tape into the stylet.

19. The surgical instrument of claim 17, wherein the tape comprises a material including multifilament strands.

20. The surgical instrument of claim 19, wherein the tape comprises polypropylene strands.

21. The surgical instrument of claim 3, wherein the material comprises a generally flat tape and the stylet has a proximal end adapted to receive an end of the tape.

22. The surgical instrument of claim 20, wherein the stylet is positioned in the tubular member so that the proximal end of the stylet is located adjacent a proximal end of the tubular member.

23. The surgical instrument of claim 3, wherein the stylet has a distal end that is blunt.

24. The surgical instrument of claim 22, wherein the distal end comprises a blunt conical tip.

25. The surgical instrument of claim 3, wherein the stylet has a distal end that is sharp.

26. The surgical instrument of claim 1, further comprising the material and wherein the material comprises an absorbable material.

27. A surgical instrument for passing a material into a body in a minimally invasive procedure, comprising a first member having a longitudinal section defining a longitudinal axis and an arcuate section extending distally from the longitudinal section, the arcuate section being dimensioned and curved whereby when in use and in position in the body,

**REPLACED BY
ART 34 AMDT**

the arcuate section extends from the skin over the obturator foramen, through the obturator foramen, to the vaginal wall.